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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,342	03/16/2001	Jan G. Tonnies	1497.4	7932

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EXAMINER	
THISSELL, JEREMY	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 01/05/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/787,342	TONNIES, JAN G.	
	Examiner	Art Unit	
	Jeremy T. Thissell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

Claim 6 objected to because of the following informalities: in line 6, the word "administrated" should likely be "administered." Appropriate correction is required.

Claim Rejections - 35 USC § 102 or 103

Claim 6 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Langley et al (US 5,421,812).

Langley teaches a method for controlling the infusion of a therapeutic agent, using a microcontroller (col. 3, line 1), based on the half-life of the agent (col. 3, line 9) as a factor in determining the total amount of agent remaining in the patient (col. 3, lines 13-14). One reason cited for monitoring and controlling the amount of agent is to ensure the safety of the patient (col. 6, line 41). Since the device is automatically controlled with a microcontroller, it is inherent that the amount of agent in the body is compared to a predetermined safety threshold, above (or below) which the patient is in danger of overdose (and/or as is also the case in Langley, who infuses anticoagulent during blood transfusions, underdose, which is also dangerous in that case).

If Applicant does not agree that these limitations are inherently met by the disclosure of Langley, then the Examiner takes the position that these limitations would have been obvious to one of ordinary skill in the art as a well-known safety system of automatic infusion machines.

Claim Rejections - 35 USC § 103

Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacouto (US 5,305,745) in view of Langley et al (US 5,421,812).

Zacouto teaches an implantable pump device having an external remote control means (col. 15, lines 50-56). Zacouto teaches determination of frequency of monitoring measurements based on the half-life of the agent being infused. Zacouto also teaches that the measurements can be intermittent or continuous. However, Zacouto does not teach that the calculations of the amount of agent in the body are made based on the half-life of the agent

Langley teaches calculation of the amount of agent based on the half-life. It would have been obvious to one of ordinary skill in the art, to utilize such calculation for the device of Zacouto, even as a secondary means of determining how much agent is in the body of the patient. Even though actual measurement as in Zacouto would be more accurate, the calculation would be a "safer" quantity to fall back on, in the event that the measuring means malfunctioned and took an accurate measurement. For example, if the measuring means somehow mistakenly registered a reading much lower than the actual amount in the body, then the infusion system would continue to add agent to the patient, which could actually push the level of agent in the patient over the safety threshold. However, the calculation of what "should" be left in the patient, after a particular time period, would at least give a rough estimate, which although it might not be as accurate, is much more reliable, than a measuring device.

Further, since the measurements can be taken intermittently, the computer may assume (without further notice, such as from the measurement) that the patient needs a predetermined amount of the agent, as is well-known in the art.

Response to Arguments

Applicant's arguments filed 8 September have been fully considered but they are not persuasive.

Applicant argued that Langley lacked a computer for calculating the maximum permitted quantity to be administered each time as a function of any previously delivered quantity and the expedited (expected?) breaking down rate of the medicament. The examiner points to Langley's microcontroller at col. 3, l. 1, which determines the maximum permitted quantity to be determined according to the "safety of the patient" (col. 6, l. 41), by determining the quantity in the patient using the half-life of the medicament (col. 3, line 9).

Applicant argued that Langley lacked a blocking device to preventing further administration of the medicament. The examiner points to the flow controller in col. 4, line 17. In view of the discussion about patient safety in col. 6, one of ordinary skill in the art would recognize (or find it obvious) that the flow controller would slow down and/or stop the flow of medicament if the quantity of medicament exceeded the safety threshold.

Applicant argued that Langley lacked a computer storing a quantitative amount of total delivered medicament less a quantity entered in the memory resulting from an

expected breaking down of the medicament in the body. However, Langley teaches a microprocessor (col. 4, line 16), which determines the amount of medicament in the body by using the half-life (breakdown rate). This inherently means that one must know the total amount delivered before using the half-life to determine what is left after a period of time.

Applicant argued that Langley lacked a comparator comparing the quantity entered in the memory with a predetermined, permitted maximum value. The fact that Langley teaches microprocessor controlled infusion based on a feedback control loop according to patient safety parameters, inherently (or obviously) means that there is a maximum amount of medicament above which it is unsafe for the patient to have in the body.

Applicant argued that references cannot subtract a fixed percentage of the medicament quantity entered in the memory. However, since Zacouto measures the amount of medicament intermittently, (col. 14, lines 44-45), which means that to determine the amount in the body, the device would simply subtract a fixed value from the total previously measured. If the system uses half-life (col. 14, l. 40; or Langley), then the fixed value would be a percentage.

Lastly, applicant argued that the references lack a second computer for operating the external control device. Zacouto teaches that the device can have multiple microprocessors that control various aspects of the device (col. 41, lines 35 and 42). Since having multiple computers for a single device is a concept routine in the art, it

would have been obvious to include a separate microprocessor for the remote control means discussed in col. 15, lines 55-56.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for all fax communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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December 31, 2003